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**PATENT**

Attorney Docket No. A-71608/TAL/DHR

Dorsey File No. 465174-00460

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

*In re* application of:

ALLISON *et al.*

Serial No.: 10/600,997

Filing Date: June 20, 2003

For: *Compositions and Methods for  
Modulating Lymphocyte Activity*

Examiner: Not Yet Assigned

Art Unit: 1653

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence, including listed enclosures, is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

Dated: July 29, 2004

Signed:   
Lukas Szymanski

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
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P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In satisfaction of the duty of disclosure under 37 C.F.R. § 1.56, and in accordance with the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants wish to draw the attention of the U.S. Patent and Trademark Office to the references cited on the accompanying form PTO/SB/8A. Copies of these references are enclosed.

Further, in accordance with the provisions of 37 C.F.R. §§ 1.97(c) and 1.97(e)(1), the undersigned certifies that the references listed on the enclosed substitute for form PTO-1449 marked with an asterisk (\*) were first cited in an International Search Report dated February 11, 2004, for counterpart PCT application PCT/US03/19614. A copy of the International Search Report for the counterpart PCT application is enclosed herewith.

Serial No.: 10/600,997  
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None of the foregoing references are believed to disclose the invention as claimed.

Nothing herein shall constitute an admission concerning the contents of any of the cited references, nor shall the inclusion of a reference herein be considered an admission that the reference constitutes prior art against the invention claimed in the above-identified application.


Submission of the present document shall not be construed as an admission that a search has been made or that better art does not exist.

As far as is known to the undersigned, this Information Disclosure Statement is being filed within three months of the filing date of a national application, within three months of the date of entry of the national state in an international application, or before the mailing date of a first Office Action on the merits as set forth in 37 C.F.R. § 1.97(b), and therefore no fee is required. While no further fee is believed to be due, if this belief is in error, the Commissioner is authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-2319 (Our Order No. 465174-00460 (A-71608/TAL/DHR)).

If there are any questions with regard to the foregoing, please call applicant's attorney at 415-781-1989.

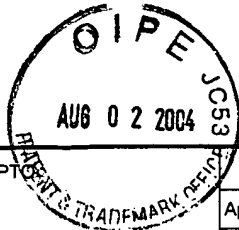
Respectfully submitted,  
DORSEY & WHITNEY LLP

Dated: 28 July 2004  
Customer Number: 32940  
Dorsey & Whitney LLP  
Four Embarcadero Center, Suite 3400  
San Francisco, CA 94111-4187  
Telephone: (415) 781-1989  
Facsimile: (415) 398-3249

By:   
Todd A. Lorenz, Reg. No. 39,754

Serial No.: 10/600,997  
Filing Date: June 20, 2003

Attachments: PTO/SB-8A/B, Substitute for form PTO-1449  
51 cited references  
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(Modified)

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

### Complete if Known

Application Number	10/600,997
Filing Date	June 20, 2003
First Named Inventor	ALLISON, James P.
Art Unit	1653
Examiner Name	To Be Assigned
Attorney Docket Number	A-71608/TAL/DHR (465174-00460)

Sheet	1	of	3
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### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	2002/0071839 A1	06-13-2002	Collins et al.	

### FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>2</sup> Number <sup>3</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	B1 *	WO 99/40100 A1	08-12-1999	Human Genome Sciences, Inc.		
	B2 *	WO 02/072794 A2	09-19-2002	Incyte Genomics, Inc.		
	B3	WO 04/000221 A2	12-31-2003	The Regents of the University of California		
	B4	WO 02/06317 A2	01-24-2002	Corixa Corp.		
	B5	WO 02/10187 A1	02-07-2002	Mayo Foundation for Medical Education and Research		
	B6	WO 02/02624 A2	01-10-2002	Amgen, Inc.		
	B7	WO 02/16581 A2	02-28-2002	Genentech, Inc.		
	B8	WO 02/16429 A2	02-28-2002	Genentech, Inc.		

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	C1	ABBAS, A.K., et al., "T-cell stimulation: an abundance of B7s," <i>Nat. Med.</i> 5(12):1345-1346 (Dec. 1999).	
	C2	ANDERSON, D., et al., "Paradoxical inhibition of T-cell function in response to CTLA-4 blockade; heterogeneity within the human T-cell population," <i>Nat. Med.</i> 6(2):211-214 (Feb. 2000).	
	C3	ARCECI, R., "The potential for antitumor vaccination in acute myelogenous leukemia," <i>J. Mol. Med.</i> 76:80-93 (1998).	
	C4	BODEY, B., et al., "Failure of cancer vaccines: the significant limitations of this approach to immunotherapy," <i>Anticancer Res.</i> 20(4):2665-2676 (Jul. - Aug. 2000).	
	C5	BRODIE, D., et al., "LICOS, a primordial costimulatory ligand," <i>Curr. Biol.</i> 10(6):333-336 (Mar. 2000).	
	C6	CARRENO, B.M., et al., "The B7 family of ligands and its receptors: new pathways for costimulation and inhibition of immune response," <i>Annu. Rev. Immunol.</i> 20:29-53 (2002).	
	C7	CHAMBERS, C., et al., "CTLA-4-mediated inhibition in regulation of T cell responses: mechanisms and manipulation in tumor immunotherapy," <i>Annu. Rev. Immunol.</i> 19:565-594 (2001).	
	C8	CHAMBERS, C., et al., "Thymocyte development is normal in CTLA-4-deficient mice," <i>Proc. Natl. Acad. Sci. USA</i> 94(17):9296-9301 (Aug. 1997).	
	C9	CHAPOVAL, A.I., et al., "B7-H3: a costimulatory molecule for T cell activation and IFN- $\gamma$ production," <i>Nat. Immunol.</i> 2(3):269-274 (Mar. 2001).	

Examiner Signature	Date Considered
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the complete application form to the USPTO. Time will vary depending on the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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		Application Number	10/600,997		
		Filing Date	June 20, 2003		
		First Named Inventor	ALLISON, James P.		
		Art Unit	1653		
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Sheet	2	of	3	Attorney Docket Number	A-71608/TAL/DHR (465174-00460)

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Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		† <sup>6</sup>
	C10	CHRISTADOSS, P., et al., "Animal models of Myasthenia gravis," <i>Clin. Immunol.</i> 94(2):75-87 (Feb. 2000).		
	C11	COYLE, A.J., et al., "The expanding B7 superfamily: increasing complexity in costimulatory signals regulating T-cell function," <i>Nat. Immunol.</i> 2(3):203-209 (Mar. 2001).		
	C12	DAMLE, N., et al., "Costimulation of T lymphocytes with integrin ligands intercellular adhesion molecule-1 or vascular cell adhesion molecule-1 induces functional expression of CTLA-4, a second receptor for B7," <i>J. Immunol.</i> 152:2686-2697 (1994).		
	C13	DONG, H., et al., "B7-H1, a third member of the B7 family, co-stimulates T-cell proliferation and interleukin-10 secretion," <i>Nat. Med.</i> 5(12):1365-1369 (Dec. 1999).		
	C14	DUDLEY, M.E., et al., "Cancer regression and autoimmunity in patients after clonal repopulation with anti-tumor lymphocytes," <i>Science</i> 268(5594):850-854 (Oct. 2002).		
	C15	EGEN, J.G., et al., "CTLA-4: new insights into its biological function and use in tumor," <i>Nat. Immunol.</i> 3(7):611-618 (Jul. 2002).		
	C16	FREEMAN, G.J., et al., "Engagement of the PD-1 immunoinhibitory receptor by a novel B7 family member leads to negative regulation of lymphocyte activity," <i>J. Exp. Med.</i> 192(7):1027-1034 (Oct. 2000).		
	C17	GAO, P., et al., "Tumor vaccination that enhances antitumor T-cell responses does not inhibit the growth of established tumors even in combination with interleukin-12 treatment: the importance of inducing intratumoral T-cell migration," <i>J. Immunother.</i> 23(6):643-653 (2000).		
	C18	GRIBBEN, G., et al., "Alloantigen and concomitant CTLA4 signaling induces clonal deletion of alloreactive T cells: a novel method to prevent GVHD," <i>Blood</i> 84(10):397a (1994).		
	C19	HESLOP, H., "Cytokine gene transfer in the therapy of malignancy," <i>Baillière Clin. Haematol.</i> 7(1):135-151 (Mar. 1994).		
	C20	KEARNEY, E., et al., "Antigen-dependent clonal expansion of a trace population of antigen-specific CD4+ T cells <i>in vivo</i> is dependent on CD28 costimulation and inhibited by CTLA-4," <i>J. Immunol.</i> 155(3):1032-1036 (Aug. 1995).		
	C21	KRUMMEL, M., et al., "Superantigen responses and co-stimulation: CD28 and CTLA-4 have opposing effects on T cell expansion <i>in vitro</i> and <i>in vivo</i> ," <i>J. Exp. Med.</i> 182(2):459-465 (Aug. 1996).		
	C22	LATCHMAN, Y., et al., "PD-L2 is a second ligand for PD-1 and inhibits T cell activation," <i>Nat. Immunol.</i> 2(3):261-268 (Mar. 2001).		
	C23	LEACH, D., et al., "Enhancement of antitumor immunity by CTLA-4 blockade," <i>Science</i> 271(5256):1734-1739 (Mar. 1996).		
	C24	LEE, K.-H., et al., "Increased vaccine-specific T cell frequency after peptide-based vaccination correlates with increased susceptibility to <i>in vitro</i> stimulation but does not lead to tumor regression," <i>J. Immunol.</i> 163(11):6292-6300 (Dec. 1999).		
	C25	LEWIS, G., et al., "Growth regulation of human breast and ovarian tumor cells by heregulin: evidence of the requirement of ErbB2 as a critical component in mediating heregulin responsiveness," <i>Cancer Res.</i> 56:1457-1465 (Mar. 1996).		
	C26	LIANG, P., et al., "The right place at the right time: novel B7 family members regulate effector T-cell responses," <i>Curr. Opin. Immunol.</i> 14(3):384-390 (Jun. 2002).		
	C27	LING, V., et al., "Cutting Edge: Identification of GL50, a novel B7-like protein that functionally binds to ICOS receptor," <i>J. Immunol.</i> 164(4):1653-1657 (Feb. 2000).		
	C28	NISHIMURA, H., et al., "PD-1: an inhibitory immunoreceptor involved in peripheral tolerance," <i>Trends Biotechnol.</i> 22(5):265-268 (May 2001).		

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	C29	PARDOLL, D.M., et al., "Tumor reactive T cells get a boost," <i>Nat. Biotechnol.</i> 20(12):1207-1208 (Dec. 2002).		
	C30	SOTOMAYOR, E., et al., "In vivo blockade of CTLA-4 enhances the priming of responsive T cells but fails to prevent to induction of tumor antigen-specific tolerance," <i>Proc. Natl. Acad. Sci. USA</i> 96(20):11476-11481 (Sep. 1999).		
	C31	SUN, M., et al., "Characterization of mouse and human B7-H3 genes," <i>J. Immunol.</i> 168(12):6294-6297 (Jun. 2002).		
	C32	SUSSMAN, J., et al., "Activation of T lymphocytes for the adoptive immunotherapy of cancer," <i>Ann. Surg. Oncol.</i> 1(4):296-306 (Jul. 1994).		
	C33	SWALLOW, M.M., et al., "B7h, a novel costimulatory homolog of B7.1 and B7.2, is induced by TNF $\alpha$ ," <i>Immunity</i> 11(4):423-432 (Oct. 1999).		
	C34	TIMMERMAN, J., et al., "Dendritic cell vaccines for cancer immunotherapy," <i>Annu. Rev. Med.</i> 50:507-529 (1999).		
	C35	TRIOZZI, P., et al., "Clinical and immunologic effects of a synthetic $\beta$ -human chorionic gonadotropin vaccine," <i>Int. J. Oncol.</i> 5:1447-1453 (1994).		
	C36	TSENG, S.Y., et al., "B7-DC, a new dendritic cell molecule with potent costimulatory properties for T cells," <i>J. Exp. Med.</i> 193(7):839-846 (Apr. 2001).		
	C37	WALLACK, M., et al., "Active specific immunotherapy with vaccinia melanoma oncolysate," <i>Immunity</i> 1(5):405-413 (Aug. 1994).		
	C38	WANG, S., et al., "Costimulation of T cells by B7-H2, a B7-like molecule that binds ICOS," <i>Blood</i> 96(8):2808-2813 (Oct. 2000).		
	C39	YANG, Y., et al., "Enhanced induction of antitumor T-cell by cytotoxic T lymphocyte-associated molecule-4 blockade: The effect is manifested only at the restricted tumor-bearing stages," <i>Cancer Res.</i> 57:4036-4041 (Sep. 1997).		
	C40	YOSHINAGA, S.K., et al., "T-cell co-stimulation through B7RP-1 and ICOS," <i>Nature</i> 402(6763):827-832 (Dec. 1999).		
	C41	ZAKS, T., et al., "Immunization with a peptide epitope (p369-377) from HER-2/neu leads to peptide-specific cytotoxic T lymphocytes that fail to recognize HER-2/neu+ tumors," <i>Cancer Res.</i> 58:4902-4908 (Nov. 1998).		
	C42	ZHU, J., et al., "Cytotoxic T lymphocyte-associated antigen 4 (CTLA-4) blockade enhances incidence and severity of experimental autoimmune neuritis in resistant mice," <i>J. Neuroimmunol.</i> 115(1-2):111-117 (Apr. 1999).		

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